

A randomised study of 'bluelight' hexyl aminolevulinic acid (HAL) photodynamic assisted resection of bladder tumours versus conventional 'whitelight' transurethral resection of newly diagnosed bladder tumours comparing rates of tumour recurrence over one year - a Phase IV trial

Submission date 25/07/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 02/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/11/2015	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

04/QO603/42

Study information

Scientific Title

A randomised study of 'bluelight' hexyl aminolevulinic acid (HAL) photodynamic assisted resection of bladder tumours versus conventional 'whitelight' transurethral resection of newly diagnosed bladder tumours comparing rates of tumour recurrence over one year - a Phase IV trial

Study objectives

The aim is to determine if photodynamic assisted resection can reduce the recurrence rate of tumour at one year when compared with the control group. The primary endpoint is the diagnosis of recurrent tumour at 3 months or 12 months on check cystoscopy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bladder cancer

Interventions

Intervention: Pre-operative intravesical instillation of solution of hexylaminolevulinic acid (HAL) - photodynamic 'bluelight' assisted resection of bladder tumours

Control: Conventional 'whitelight' transurethral resection

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Hexyl aminolevulinic acid (HAL)

Primary outcome(s)

Recurrence rates of bladder tumour at 3 months and 12 months post surgery

Key secondary outcome(s)

Analysis of histology

Completion date

01/02/2007

Eligibility

Key inclusion criteria

1. New diagnosis of bladder tumour - the study is designed to reduce recurrence rates in newly diagnosed cases of bladder tumours
2. Superficial disease - the study will address the recurrence rates in superficial bladder cancer
3. No history of previous bladder surgery - previous surgical procedures to the bladder may cause artifactual changes when using 'blue light' cystoscopy
4. Life expectancy of at least 1-year - study duration will be for 1-year

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Previous bladder tumour or coexisting/previous upper tract disease - the study is designed to reduce recurrence rates in newly diagnosed cases of bladder tumours
2. Muscle invasive disease - the study will address the recurrence rates in superficial bladder cancer
3. Previous bladder surgery -previous surgical procedures to the bladder may cause artifactual changes when using 'blue light' cystoscopy

Date of first enrolment

01/02/2005

Date of final enrolment

01/02/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Guy's Hospital

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

Guy's Hospital - Research and Development Department (UK)

ROR

<https://ror.org/04r33pf22>

Funder(s)

Funder type

Charity

Funder Name

Guy's and St Thomas' Charity (UK)

Alternative Name(s)

Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2013		Yes	No